

## **REMARKS**

The office action dated July 21, 2008 has been reviewed and the comments of the examiner have been considered. Prior to this paper, claims 1-60 were pending. By this paper applicant further amends claims 1 -3, 5, 6, 8, 9, 26, 27, cancels claims 4, 7, 10-25, and 28-60 and adds new claims 61 and 62. Therefore claims 1-3, 5, 6, 8, 9, 26, 27, 61, and 62 are currently pending. New claim 61 is the only independent claim pending in the current application. The pending claims with cancelled claims omitted are listed in Addendum 1 (page 22). The pending claims with cancelled claims omitted are listed in logical order in Addendum 2 (page 26).

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

### **Rejections based on Double Patenting**

Claims 1-60 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of US 6,932,796. Applicant respectfully traverses this rejection as follows. In the present application, all claims are based on an optical system geometry where the sense beam of light passes completely through the passageway. In US 6,932,796 all the claims are based on an optical system geometry where the sense beam of light is reflected from the first passageway-fluid interface. Indeed, in US 6,932,796 light that is not reflected is not discussed; it is merely shown in the figures as passing away from the point of reflection. Since in US 6,932,796 the claims are all based on reflection of the sense beam and in the present case none of

the claims are based on reflection of the sense beam, it is not possible for the present application and US 6,932,796 to claim similar subject matter.

Claims 1-60 were also rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of US 7,268,859. Applicant respectfully traverses this rejection as follows. In the present application, all claims are based on an optical system comprising a sense beam path without a reference path. All the claims of US 7,268,859 are based on an optical system wherein the sense laser beam is split to comprise both a direct path through the liquid in the passageway and a reference path that does not pass through the liquid in the passageway. Further, the split beams are later combined in order to create optical interference. Furthermore, all of the claims in US 7,268,859 are based on the optical process of interference of a sense beam split so that a first path passes through the fluid and a second path that does not pass through the fluid. In the present application, none of the claims are based on the optical process of interference and no split sense beam is described. Since the optical systems of the present application and US 7,268,859 are different, and since the claims are based on different optical processes, it is not possible for the present application and US 7,268,859 to claim similar subject matter.

#### **Rejections based on Obviousness (35 USC § 103)**

Claims 1-25, 31-48 and 51-60 have been rejected under 35 USC § 103 as being unpatentable over Yin et. al. in US 6,386,050 in view of Fritz (US 2007/0188737).

Claims 4, 7, 10 - 25, 28 - 60 have been cancelled, therefore the following remarks only relate to examiners rejection of previously pending claims 1-3, 5, 6, 8, 9, 26 and 27 and new claims 61 and 62.

Applicant added new claims 61 and 62 and has made new claim 61 the only independent claim in the current application. Applicant has also made claims 1 – 3, 5, 6, 8, 9, 26, 27, and 62 dependent on claim 61. Applicant respectfully traverses the rejection of previously pending claims 1 – 3, 5, 6, 8, 9, 26, 27, by making the currently pending claims 1 -3, 5, 6, 8, 9, 26, 27, and new claim 62 dependent on new claim 61. Examiner's attention is drawn to the fact that the process of diffraction is no longer a limitation in any of the pending claims.

### **Regarding Allowability of Pending claims**

Applicant believes all of the pending claims are allowable in light of the prior art. In previous office actions examiner has rejected claims either as anticipated by Yin (US 6,386,050) or obvious in light of Yin and other prior art. Applicant offers the following reasons why the pending claims as amended are allowable.

With regard to rejection of new claim 1 based on anticipation by Yin, applicant relies on MPEP § 2132 which states that “a claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently described in a single art reference”.

With regard to express description of claim 1 by Yin in US 6,386,050, Yin does not describe a temperature variation in the thermal marker that he creates, either at the first location where it is created or at the second location where it is sensed. The

temperature distribution of the heated fluid, not only in physical extent along the passageway but more importantly as a function of position across the fluid stream is a major limitation in Applicant's new independent claim. Thus Yin does not expressly describe each and every element of Applicant's first claim.

With regard to the limitations claimed by Applicant in new claim 61 being inherent in the system described by Yin, or in systems in the prior art, Applicant relies on MPEP § 2112 section IV:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.

Some of the best examples of the limitation in new claim 61 not being inherent are provided in Yin (US 6,386,050) and in selected other prior art. The first example is shown in Figure 1 of Yin. An inductive heater 20 is shown surrounding the conduit and fluid 12. The conduit of Figure 1 is frequently made of metal, especially in the fields of chromatography as cited by Yin (column 1 lines 13-20). Metal heats much more rapidly than fluid in an inductive heater, hence the fluid will have a temperature variation where the fluid beside the wall is warmer than the fluid at the center of the stream. Indeed—Yin relies on this feature of the temperature variation in the fluid when he describes light redirection by a change in the index of refraction of the fluid at the fluid/wall interface (Column 3, lines 45 – 49, Column 7, lines 8 – 33, Figure 4). Yin also describes a heater embedded in the wall of the passageway (column 4 lines 43 - 46) which will also cause higher fluid temperatures beside the wall.

A second example is the description of heating the fluid in Frank (5,211,626 column 7 lines 45-56. In this case the liquid is heated by supplying electrical power to a resistive element in clip 53 which is in thermal contact with the wall of the conduit. Heat

is conducted through the wall to heat the fluid, again resulting in the temperature of the fluid being warmer beside the wall than at the center of the fluid stream.

A third example of lack of inherence of a temperature distribution that is warmer in the center of the stream than near the wall is provided by Jerman (US 5,533,412 Figures 1 & 2 and column 4 lines 1-42). As in the previous references, the thermal marker is created using heaters that are in contact with the wall but not the fluid. Heating the fluid occurs by conduction of heat through the wall resulting in a temperature distribution in the fluid which is warmer at the wall than at the center of the fluid stream. With these examples, Applicant shows that the limitation of a fluid temperature variation from the passageway wall to the center of the passageway where the temperature of the fluid in the stream is cooler beside the wall of the passageway than at the center is not inherent.

Thus Applicant argues that each and every element as set forth in new claim 61 is not found either expressly or inherently described in a single art reference. And since Applicant's remaining claims are dependent on claim new claim 61, neither Yin nor the prior art can anticipate these claims either.

With regard to obviousness, applicant relies on MPEP § 2143 which states:

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

Is there some suggestion or motivation in Yin (6,386,050) or in knowledge generally available to one skilled in the art to modify Yin to achieve applicant's

invention? Applicant argues that there is not. As described above in relation to anticipation, Yin in 6,386,050 and the other cited examples actually teach away from the applicant's art because of the way the thermal marker is created and the temperature variation across the passageway that it results. Yin and prior art teach the creation of the thermal marker using heat from a heated wall. In the case of Yin, having a temperature variation where the fluid near the wall is warmest (as opposed to Applicant's art where the warmest temperatures are near the center of the stream) is desirable since the redirection of light in the sense beam occurs at the interface between the fluid and the passageway wall. Since Yin teaches away, there is no suggestion or motivation to one skilled in the art to use Yin or to use Yin in combination with any other prior art to arrive at Applicant's art.

Is there a reasonable expectation of success? Since there is no suggestion or motivation to modify Yin, since Yin teaches away, and since in the art of Yin there is a preference for warmer temperatures near the wall in order to facilitate light redirection at the fluid/wall interface, the expectation would be for failure rather than success.

Do the prior art reference(s) teach or suggest all the claim limitations? As argued above in the paragraphs related to anticipation, Yin does not teach all the claims limitations. And since Yin actually teaches away from Applicant's invention, all of the claim limitations are not suggested by Yin or by Yin in combination with other prior art.

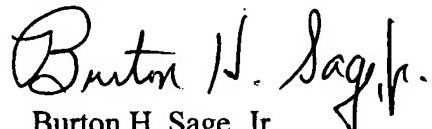
### **Conclusion**

Applicant believes that the present application is now in condition for allowance.

Favorable reconsideration of the application as amended is respectfully requested.

Examiner Schell is invited to contact the undersigned by email or phone if it is felt that a dialog would advance the prosecution of the present application.

Respectfully submitted



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## Addendum 1

### Amended Claims with cancelled claims omitted in numerical order

1. (Currently amended) A The system for monitoring fluid flow along a passageway of claim 61 comprising wherein the temperature of the exposed fluid near the center of the passageway is higher than the temperature of the exposed fluid beside the wall of the passageway at the second position along the passageway.
  - a) a heater that heats a portion of the fluid in the passageway,
  - ~~b) a light source that generates a beam of light the illuminates the fluid in the passageway, and~~
  - ~~c) a light detector positioned to receive a portion of the beam wherein the detector measures a change in the intensity of the beam caused by diffraction of the beam by the heated portion of the fluid that passes through the beam.~~
2. (Currently amended) The system of claim + 62 wherein the beam has an axis and the light detector is positioned along the optical axis such that the light detector measures a decreased intensity with the passage of the heated exposed portion of the fluid.
3. (Currently amended) The system of claim + 62 wherein the beam has an axis and the light detector is displaced from the optical axis such that the light detector measures an increased intensity with the passage of the heated exposed portion of the fluid.

5. (Currently amended) The system of claim 4 62 wherein the heater is an infrared laser.
6. (Currently amended) The system of claim 4 62 wherein the fluid is a liquid.
8. (Currently amended) The system of claim 4 62 further comprising a processor that measures a time period between ~~heating of~~ exposing the portion of the fluid and detection of the passage of the ~~heated~~ exposed portion of the fluid by the light detector.
9. (Currently amended) The system of claim 8 wherein the processor calculates a velocity of the fluid from the time period and the known distance between ~~the heater~~ the first position and the second position. ~~light source~~.
26. (Currently amended) A device for delivery of a liquid medicament to a subject comprising:
  - a system for monitoring fluid flow through a passageway according to claim 4 9 and
  - a valve for ~~starting and stopping~~ adjusting the rate of liquid flow in the flow tube along the passageway in a periodic manner based on the calculated velocity.  
~~information from the system.~~
27. (Currently amended) A device for delivery of a liquid medicament to a subject comprising:

a system for monitoring fluid flow through a passageway according to claim 9;

and

a valve for starting and stopping liquid flow in the flow tube in a periodic manner based on the calculated velocity, information from the system.

61. (new) A system for monitoring fluid flow along a passageway comprising:

- a) a source of radiation adapted to expose a portion of the fluid in the passageway to the radiation at a first position along the passageway such that at the first position the temperature of the exposed fluid beside a wall of the passageway is lower than the temperature of the exposed fluid nearer the center of the passageway;
- b) a light source that generates a beam of light that illuminates the fluid at a second downstream location along the passageway; and
- c) a light detector positioned to receive a portion of the beam, wherein the detector measures a change in the intensity of the beam when the exposed portion of the fluid passes through the beam.

62. (new) The system of claim 1 wherein the beam has an optical axis that is at a right angle to the passageway.

## Addendum 2

### **Amended Claims with cancelled claims omitted in logical order**

61. (new) A system for monitoring fluid flow along a passageway comprising:

- a) a source of radiation adapted to expose a portion of the fluid in the passageway to the radiation at a first position along the passageway such that at the first position the temperature of the exposed fluid beside a wall of the passageway is lower than the temperature of the exposed fluid nearer the center of the passageway;
- b) a light source that generates a beam of light that illuminates the fluid at a second downstream position along the passageway; and
- c) a light detector positioned to receive a portion of the beam, wherein the detector measures a change in the intensity of the beam when the exposed portion of the fluid passes through the beam.

1. (Currently amended) A The system for monitoring fluid flow along a passageway of claim 61 comprising wherein the temperature of the exposed fluid near the center of the stream is higher than the temperature of the exposed fluid beside the wall of the passageway at the second position along the passageway.

- ~~a) a heater that heats a portion of the fluid in the passageway,~~
- ~~b) a light source that generates a beam of light that illuminates the fluid in the passageway, and~~

— e) a light detector positioned to receive a portion of the beam wherein the detector measures a change in the intensity of the beam caused by diffraction of the beam by the heated portion of the fluid that passes through the beam.

62. (new) The system of claim 1 wherein the beam has an optical axis that is at a right angle to the passageway.

2. (Currently amended) The system of claim 1 62 wherein the beam has an axis and the light detector is positioned along the optical axis such that the light detector measures a decreased intensity with the passage of the heated exposed portion of the fluid.

3. (Currently amended) The system of claim 1 62 wherein the beam has an axis and the light-detector is displaced from the optical axis such that the light detector measures an increased intensity with the passage of the heated exposed portion of the fluid.

5. (Currently amended) The system of claim 1 62 wherein the heater is an infrared laser.

6. (Currently amended) The system of claim 1 62 wherein the fluid is a liquid.

8. (Currently amended) The system of claim 1 62 further comprising a processor that measures a time period between heating of the portion of the fluid and detection of the passage of the heated exposed portion of the fluid by the light detector.

9. (original) The system of claim 8 wherein the processor calculates a velocity of the fluid from the time period and the known distance between the heater and the light source.

26. (Currently amended) A device for delivery of a liquid medicament to a subject comprising:

a system for monitoring fluid flow through a passageway according to claim + 9  
and

a valve for starting and stopping adjusting the rate of liquid flow ~~in the flow~~  
~~tube along the passageway in a periodic manner based on the calculated velocity.~~  
~~information from the system.~~

27. (Currently amended) A device for delivery of a liquid medicament to a subject comprising:

a system for monitoring fluid flow through a passageway according to claim 9;  
and

a valve for starting and stopping liquid flow in the flow tube in a periodic manner  
based on the calculated velocity. ~~information from the system.~~